

guidance document identified in this rule.

## II. Environmental Impact

The agency has determined under 21 CFR 25.22 and 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

## III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the final rule is not a significant regulatory action as defined by the Executive order and so it is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Classification of these devices into class II will relieve manufacturers of the device of the cost of complying with the premarket approval requirements of section 515 of the act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by lowering their costs. The agency, therefore, certifies that the final rule will not have a significant impact on a substantial number of small entities. In addition, this final rule will not impose costs of \$100 million or more on either the private sector or State, local, and tribal governments in the aggregate and, therefore, a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform Act is not required.

## IV. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National

Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

## V. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

## VI. Reference

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petition from Roche Diagnostics Corp., dated December 8, 2003.

## List of Subjects in 21 CFR Part 864

Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 864 is amended as follows:

### PART 864—HEMATOLOGY AND PATHOLOGY DEVICES

■ 1. The authority citation for 21 CFR part 864 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Section 864.1 is amended by adding paragraph (d) to read as follows:

#### § 864.1 Scope.

\* \* \* \* \*

(d) Guidance documents referenced in this part are available on the Internet at <http://www.fda.gov/cdrh/guidance.html>.

■ 3. Section 864.7280 is added to subpart H to read as follows:

#### § 864.7280 Factor V Leiden DNA mutation detection systems.

(a) *Identification.* Factor V Leiden deoxyribonucleic acid (DNA) mutation detection systems are devices that consist of different reagents and instruments which include polymerase chain reaction (PCR) primers, hybridization matrices, thermal cyclers, imagers, and software packages. The detection of the Factor V Leiden mutation aids in the diagnosis of patients with suspected thrombophilia.

(b) *Classification.* Class II (special controls). The special control is FDA's guidance entitled "Class II Special Controls Guidance Document: Factor V Leiden DNA Mutation Detection Systems." (See § 864.1(d) for the availability of this guidance document.)

Dated: March 5, 2004.

**Beverly Chernaik Rothstein,**

*Acting Deputy Director for Policy and Regulations, Center for Devices and Radiological Health.*

[FR Doc. 04–5864 Filed 3–15–04; 8:45 am]

**BILLING CODE 4160–01–S**

## PEACE CORPS

### 22 CFR Part 302

#### Organization

**AGENCY:** Peace Corps.

**ACTION:** Final rule.

**SUMMARY:** The Peace Corps is removing from the Code of Federal Regulations its regulation on Peace Corps' organization. The regulation is outdated and unnecessary. Information on the Peace Corps' organization is already published and updated annually in the *United States Government Manual*, a special **Federal Register** publication.

**DATES:** The rule will be effective on April 15, 2004.

**FOR FURTHER INFORMATION CONTACT:** Tyler S. Posey, General Counsel, (202) 692–2150.

**SUPPLEMENTARY INFORMATION:** This final rule removes 22 CFR part 302 from the Code of Federal Regulations because it is outdated and unnecessary. Information on Peace Corps' organization is annually updated and published in the **Federal Register's** "United States Government Manual." See FOIA Update, Summer 1992 (Office of Information and Privacy, Department of Justice).

*Matters of Regulatory Procedure.* Executive Order 12866. The Peace Corps has determined that this final rule does not constitute a "significant regulatory action" for the purposes of Executive Order 12866.

*Regulatory Flexibility Act.* Pursuant to section 605(b) of the Regulatory Flexibility Act, the Peace Corps certifies that this rule will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Accordingly, no regulatory flexibility analysis is required.

**List of Subjects in 22 CFR Part 302**

Organization and functions;  
government agencies.

**PART 302—[REMOVED]**

■ For the reasons set forth in the preamble, the Peace Corps amends title 22 of the CFR by removing part 302.

Dated: March 10, 2004.

**Tyler S. Posey,**  
*General Counsel.*

[FR Doc. 04-5831 Filed 3-15-04; 8:45 am]

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**DEPARTMENT OF EDUCATION**

**34 CFR Parts 600, 649, 668, 674, 675, 676, 682, 685, 690 and 693**

**RIN 1840-AC47**

**Institutional Eligibility Under the Higher Education Act of 1965, as Amended (HEA); Patricia Roberts Harris Fellowship Program; Student Assistance General Provisions; Federal Perkins Loan Program; Federal Work-Study Programs; Federal Supplemental Educational Opportunity Grant Program; Federal Family Education Loan Program; William D. Ford Federal Direct Loan Program; Federal Pell Grant Program; and National Early Intervention Scholarship and Partnership Program**

**AGENCY:** Department of Education.

**ACTION:** Final regulations.

**SUMMARY:** The Secretary amends §§ 600.55 and 600.56 of the Institutional Eligibility regulations to effectuate Pub. L. 108-98, a recent enactment with a retroactive effective date of October 1, 1998.

The Secretary also is amending the Institutional Eligibility, Patricia Roberts Harris Fellowship Program, Student Assistance General Provisions, Federal Perkins Loan Program, Federal Work-Study Programs, Federal Supplemental Educational Opportunity Grant Program, Federal Family Education Loan (FFEL) Program, William D. Ford Federal Direct Loan Program, Federal Pell Grant Program, and National Early Intervention Scholarship and Partnership (NEISP) Program regulations. These technical revisions are necessary to correct cross-references, delete references to programs that are no longer funded, and make a number of nomenclature changes that provide the correct names of various Title IV, HEA programs.

**EFFECTIVE DATE:** The amendments to §§ 600.55 and 600.56 of the Institutional

Eligibility regulations are effective retroactively to October 1, 1998. All of the other amendments take effect April 15, 2004.

**FOR FURTHER INFORMATION CONTACT:**

Lorraine Kennedy, U.S. Department of Education, 1990 K Street, NW., room 8018, Washington, DC 20006. Telephone: (202) 502-7762. Jackie Butler, U.S. Department of Education, 1990 K Street, NW., room 8062, Washington, DC 20006. Telephone: (202) 502-7890. If you use a telecommunications device for the deaf (TDD), you may call the Federal Information Relay Service (FIRS) at 1-800-877-8339.

Individuals with disabilities may obtain this document in an alternative format (e.g., Braille, large print, audiotape, or computer diskette) on request to the contact person listed under **FOR FURTHER INFORMATION CONTACT**.

**SUPPLEMENTARY INFORMATION:** The regulations governing Institutional Eligibility under the Higher Education Act of 1965, as amended, 34 CFR part 600; Patricia Roberts Harris Fellowship Program, 34 CFR part 649; the Student Assistance General Provisions regulations, 34 CFR part 668; Federal Perkins Loan Program, 34 CFR part 674; Federal Work-Study Programs, 34 CFR part 675; Federal Supplemental Educational Opportunity Grant Program, 34 CFR part 676; Federal Family Education Loan Program, 34 CFR part 682; William D. Ford Federal Direct Loan Program, 34 CFR part 685; Federal Pell Grant Program, 34 CFR part 690; and National Early Intervention Scholarship and Partnership Program, 34 CFR part 693 are amended to provide certain clarifications, to correct errors and omissions, and to remove references to Title IV, HEA programs that are no longer authorized or funded.

Sections 600.55 and 600.56 of the Institutional Eligibility regulations are revised to conform with newly-enacted Public Law 108-98. That legislation corrected technical errors in the Higher Education Amendments of 1998 by removing inadvertent barriers to institutional eligibility that applied to public and non-profit foreign veterinary schools, as well as to Canadian medical schools. Consistent with the legislation, the conforming changes to the regulations are effective retroactively to October 1, 1998.

Section 600.57(a) of the Institutional Eligibility regulations has been amended to establish the maximum duration of a program participation agreement for foreign institutions as six years from the date of the Secretary's

certification determination. This change conforms the regulations to the Higher Education Amendments of 1998, Pub. L. 105-244, which extended the maximum period of time that an institution may be certified to participate in the Title IV, HEA programs from four to six years.

These regulations remove part 649 from 34 CFR because the Patricia Roberts Harris Fellowship Program is no longer authorized by the HEA.

The expected family contribution (EFC) definition has been removed from the individual program regulations for the Federal Perkins Loan Program, Federal Work-Study Programs, Federal Supplemental Educational Opportunity Grant Program, Federal Family Education Loan Program, William D. Ford Federal Direct Loan Program, and Federal Pell Grant Program and is now listed instead in the Student Assistance General Provisions under the General Definitions in § 668.2. This change was made to centralize the definitions used in the Title IV, HEA program regulations.

We have removed the reference to the ALAS Program in the definition of Federal Supplemental Loans for Students in § 668.2 because the ALAS program is no longer authorized by the HEA.

The definition of parent in § 668.2 has been changed by deleting the discussion of "legal guardian", to conform with the definition of parent in Part F of the Higher Education Act of 1965, as amended.

The reference to the National Early Intervention Scholarship and Partnership Program (NEISP) in § 668.26(b)(5) has been removed because the program is no longer authorized by the HEA.

Section 668.26 has been amended by removing paragraphs (d)(2)(iv) and (e)(3) and redesignating paragraph (d)(2)(v) as (d)(2)(iv). Section 668.26(d)(2) lists the circumstances under which an institution whose participation in the Title IV programs has ended may disburse an FFEL Program loan. The removed paragraph required that the loan commitment be made prior to the loss of participation. However, this is redundant in light of the requirement that the first disbursement of the loan be made prior to the end of participation. The first disbursement of a loan cannot be made unless a commitment for the loan has been made. This change makes the FFEL requirement similar to the corresponding requirement for Direct Loan Program loans in § 668.26(d)(3)(iii).

These regulations make changes to the Federal Pell Grant Program regulations to move the definition of EFC to the